UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES	)	
	)	
	)	
v.	)	**CRIMINAL NO. 09-10330-GAO**
	)	
STRYKER BIOTECH, LLC, et al.,	)	
	)	
	)	
Defendants.	)	

NON-PARTY STEPHEN P. MACMILLAN'S MOTION TO QUASH TRIAL SUBPOENA OR, IN THE ALTERNTAIVE, FOR ORDER REGARDING THE SCHEDULING OF HIS APPEARANCE AT TRIAL

Non-party Stephen P. MacMillan hereby moves that the government's trial subpoena compelling him to testify at the trial of the above-entitled criminal case on January 9, 2012, be quashed or, in the alternative, that the Court enter an Order granting Mr. MacMillan relief from testifying prior to January 16, 2012.

INTRODUCTION

Steve MacMillan is the Chairman, President and Chief Executive Officer of Stryker Corporation ("Stryker"), the parent of defendant Stryker Biotech, LLC ("Biotech"). The government has subpoenaed Mr. MacMillan to testify in the trial of this case commencing on January 9, 2012. The government's subpoena to Mr. MacMillan is, regrettably, all about gamesmanship and leverage, and not at all about securing probative testimony on a material issue. The government's apparent gambit is to threaten Stryker's chief executive with the prospect of being separated from his work while he spends days preparing for his testimony, waiting in Boston for his turn to testify, and testifying -- all in the apparent hope of precipitating a tactical advantage. Beyond the government's hope

that something will "shake out" of subpoenaing Stryker's Chairman and CEO, it is anyone's guess what Mr. MacMillan really has to do with the trial of this case.

What this motion is *not* about, however, is a belief by Mr. MacMillan that he is above the law and need not participate in a criminal proceeding. Indeed, Mr. MacMillan voluntarily agreed to a government interview in 2009, and thereafter prepared for *three* separate grand jury appearances, although the government ultimately decided not to put him in the grand jury. Mr. MacMillan's "non-appearance" in the grand jury after three false starts speaks to his willingness to participate in this proceeding and speaks even more loudly to the government's apparent motives for subpoenaing Mr. MacMillan.

At bottom, no litigant -- not even the government -- can subpoena as a trial witness the Chairman and CEO of a Fortune 500 company just to see if a strategic benefit will result from the havoc thereby created. The test, of course, is whether the witness has anything relevant to say at trial, and the government fails that test with respect to Mr. MacMillan. For all of the reasons set forth below, Mr. MacMillan respectfully requests that his trial subpoena be quashed.

FACTUAL AND PROCEDURAL BACKGROUND

A. Mr. MacMillan

Steve MacMillan is in charge of Stryker's entire business operations, its 21,000+ employees, and its $7 billion of annual sales. He serves as Stryker's Chairman, President and Chief Executive Officer. Mr. MacMillan joined Stryker as its head in 2003 after a distinguished career at Johnson & Johnson and Pharmacia Corporation. In addition to his duties at Stryker, Mr. MacMillan also serves as a Director of Texas Instruments and is a member of the Department of Commerce's United States Manufacturing Council which advises the Administration on ways to create more manufacturing jobs in the United

States. In early 2012, Mr. MacMillan will assume additional duties as Chairman of AdvaMed, the single largest health care industry and ethics group representing health care companies that manufacture nearly 90 percent of the health care technology purchased annually in the United States.

B. Mr. MacMillan's Cooperation With the Government's Investigation

In April 2009, the government interviewed Mr. MacMillan in Boston. Although the 1 – 2 hour interview was wide-ranging, the government focused on Mr. MacMillan's knowledge (*vel non*) of the operations of Stryker's Biotech division, former division head Mark Philip's separation from Biotech, and Mr. MacMillan's focus on Biotech's effort to secure premarket approval for its OP-1 products.

Thereafter, the government requested that Mr. MacMillan testify in the grand jury, and Mr. MacMillan agreed to do so without a subpoena.

- The government initially scheduled his grand jury appearance for September 2, 2009. Although Mr. MacMillan prepared for the appearance by meeting with counsel and reviewing documents, the government cancelled that appearance on August 20, 2009.
- The government waited until December 2009 to renew its request for Mr. MacMillan's grand jury appearance. The parties agreed that Mr. MacMillan would testify on February 10, 2010. Mr. MacMillan again prepared for his grand jury appearance and flew to Boston for his testimony, but this appearance did not go forward because the grand jury was cancelled due to bad weather.
- The government then asked for yet *another* date for Mr. MacMillan's grand jury appearance, and a date of June 2, 2010 was scheduled. This time, just five days before his *third* scheduled appearance, the government cancelled. Ultimately, the

present case was indicted in October 2009 and Mr. MacMillan never appeared before the grand jury.

The government served a trial subpoena for Mr. MacMillan on May 3, 2011.

C. The Testimony the Government Proposes to Elicit

The government has articulated some of the areas on which it intends to focus in its proposed examination of Mr. MacMillan. The government's proposed areas of examination, and Mr. MacMillan's anticipated testimony on these topics based on the government's Report of Interview from his April 24, 2009 interview with the government, are set forth below:

1. *Government Topic #1: Where did the Biotech division fit in, in terms of Stryker's overall corporate structure?*

Anticipated MacMillan Testimony based on Memorandum of Interview: Mr. MacMillan conducted a 30-minute call every Monday morning with 20 to 25 Stryker division heads, finance people and staff. Biotech's division head, Mark Philip, was on these calls. HHS/OIG Report of Interview, at 1 ("Interview"). Mr. MacMillan also conducted quarterly (and then episodic) reviews of Biotech, where Mr. MacMillan traveled to Biotech's headquarters. Interview at 1-2. Finally, the head of the Biotech division made a presentation to Stryker's Board of Directors twice each year. Interview at 2. "Besides the Monday calls and the reviews, MacMillan had no other regular contact with Stryker Biotech." *Id.* Mr. MacMillan also received a "standard monthly memo" that each division was required to submit, including Biotech. *Id.*

2. *Government Topic #2: Describe the two products at issue: OP-1 Putty and Calstrux.*

Anticipated MacMillan Testimony based on Memorandum of Interview: The government did not ask him this specific question. Regarding OP-1 Putty, Mr. MacMillan stated that he "was always stuck that doctors loved OP-1 Putty so much *because* of its handling characteristics. Physicians loved the OP-1 Putty as it was, and much more than OP-1 Implant [emphasis in original]." Interview at 5. Regarding Calstrux, Mr. MacMillan did not know when Calstrux became a Biotech product; had no involvement in the launch or development of Calstrux, had no idea what the sales of Calstrux were, and "had no idea how many [units of Calstrux were sold] in conjunction with OP-1 versus as a stand-alone product." Interview at 5-6. "[T]he sales [of Calstrux] were so small that they did not even register in any Striker financials given that Stryker Biotech, as a whole, was so small." Interview at 6.

3. *Government Topic #3: Provide an overview of what an Humanitarian Device Exemption ("HDE") is.*

Anticipated MacMillan Testimony based on Memorandum of Interview: The government did not ask him this specific question, although he expressed general familiarity with the concept that, because OP-1 was an HDE product, its sales would be limited. *See* Interview at 2 & 6.

4. *Government Topic #4: Describe Mr. MacMillan's visit to Biotech in June 2005.*

Anticipated MacMillan Testimony based on Memorandum of Interview: "MacMillan had no independent memory of going to Hopkinton in June 2005 to attend a meeting …, but he agreed that he had no reason to doubt he was there." Interview at 6. Regarding his recollection of a slide presentation that Biotech's sales head allegedly made at the June 2005 meeting, "… MacMillan had no memory of these slides and he did not remember a discussion about Stryker Biotech selling OP-1 Putty too fast and that the company may hit its HDE cap early." *Id.*

5. *Government Topic #5: Who is Mr. MacMillan relying on at Biotech? When Mr. MacMillan is assured that Biotech is being well-run, who is assuring him? When Mr. MacMillan receives monthly information about Biotech, who is he getting it from?*

Anticipated MacMillan Testimony based on Memorandum of Interview: Although the government did not pose these specific questions to him, Mr. MacMillan said the following: "Besides the scheduled reviews and calls, it was very rare for MacMillan to have any episodic contact with [Biotech's head Mark] Philip. MacMillan's communication with Stryker Biotech took place through Jamie Kemler, Stryker's Group President of Biotech, Osteosynthesis and Development." Interview at 2.

ARGUMENT

I. THE COURT HAS THE POWER TO QUASH AN UNNECESSARY AND ABUSIVE TRIAL SUBPOENA, AND THE COURT SHOULD EXERCISE ITS DISCRETION TO DO SO IN THIS INSTANCE.

A. Legal Standard

Although there exists no specific provision in Fed. R. Crim. P. 17 that empowers a district court to quash a trial subpoena for testimony (as opposed to documents), the First Circuit has made clear that a court indeed has the power to quash a problematic trial subpoena. Noting the ubiquity with which motions to quash are litigated in the district courts, *United States v. Klubock*, 832 F.2d 649, 656 (1st Cir. 1986), the First Circuit stated

that "[t]he very fact that there exists a remedy entitled 'motion to quash or modify subpoena *ad testificandum,' sans* Rule 17, indicates that silence in the Federal rules of procedure does not necessarily mean that the courts are powerless to correct perceived problems as they arise …." *Id. See* Moore's Federal Criminal Procedure, §617.07; *see also United States v. Wallace*, 32 F.3d 921, 929 (5th Cir. 1994) (trial court's refusal to issue subpoenas to two DOJ employees "may be upheld under the trial court's power to control the trial and limit testimony that would be cumulative and marginally relevant").

"Given the case-specific nature of criminal trails," trial courts are "afforded great latitude in weighing factors such as timeliness, materiality, relevancy, competency, practicality, and utility, as a means of determining whether a subpoena request is well founded." *United States v. Nivia*, 887 F.2d 1110, 1118 (1st Cir. 1989) (upholding district court's decision denying Rule 17(b) subpoena to defendant). District Judge Gertner perhaps expressed the concept best in a recent case somewhat analogous to the present case, wherein the court quashed a criminal defendant's subpoenas seeking "CEO-type" testimony from the Secretaries of the Department of the Interior and Department of Homeland Security. ***"[I]t seems self-evident that [a party] should not be allowed to compel the appearance of a witness whose testimony would be irrelevant*** **[emphasis added]."** *United States v. Manghis*, 2010 WL 349583 (D. Mass. 2010). *See also United States v. North*, 1989 WL 9087, *1 (D.D.C. 1989) (quashing defendant's trial subpoena directed to President Bush; defendant "made no showing that President Bush has any specific information relevant and material to the charges of the indictment which makes it necessary or appropriate to require his appearance").

B. Mr. MacMillan Has No Specific, Probative and Non-cumulative Testimony to Offer at Trial.

Just because Mr. MacMillan is Stryker's Chairman, President and Chief Executive Officer, its does not make his testimony automatically relevant to "all things Biotech." Indeed, as evidenced by the side-by-side comparison of the government's proposed examination of Mr. MacMillan and his interview testimony (*supra* at 4-5), Mr. MacMillan has nothing of substance to offer on the key issue of the defendants' guilt or innocence. His inability now to offer relevant testimony about Biotech's operations is not surprising, given that he considered Biotech's sales numbers "a rounding error in the large[r] financial picture of the company ...." Interview at 4. Other than the customary reporting mechanisms that were in place for all Stryker divisions, it was "very rare" for Mr. MacMillan even to have contact with Biotech's head, Mark Philip. Interview at 2. Instead, Mr. MacMillan received his information about Biotech through Mark Philip's boss, Mr. Kemler. *Id.*

Even assuming *arguendo* that Mr. MacMillan were able to testify concerning Biotech's products and operations -- say, as the government currently proposes, regarding what an HDE is or what Calstrux was -- certainly his testimony would be far less specific and helpful to the fact-finder than other trial witnesses currently on the government's witness list, such as Biotech's former sales and marketing personnel, regulatory head, and QA/QC head. *See United States v. North*, *supra,* at 9087, *1 (no showing made that President Bush had any "specific information relevant and material" to the pending charges). Indeed, can the government seriously claim that Mr. MacMillan will be able to testify more competently on the issue of what a Humanitarian Device Exemption (or so-called "HDE") is than Biotech's former head of regulatory affairs, who is also on the government's witness list?

Should the Court, moreover, allow two pending motions, Mr. MacMillan's testimony will become event more starkly unnecessary. According to the Court's docket, defendant Biotech and the individual defendants made certain pre-trial motions (among others): Defendant's Motion *in limine* to Exclude Evidence of Mark Philip's Separation From Stryker Biotech (Docket No. 174), Defendants William Heppner, David Ard and Jeffrey Whitaker's Motion to Sever Count Fifteen Due to Misjoinder Under Fed. R. Crim. P. 8(b) (Docket Nos. 132, 133, 144, 160, 162, and 163), Defendant Stryker Biotech's Motion to Sever Count 15 (Docket Nos. 135, 136, 144, 160, 162, and 163), and Defendant Mark Philip's Motion to Sever Count 15 (Docket Nos. 137, 144, 160, 162, and 163).

Regarding the motion *in limine* to exclude evidence of defendant Mark Philip's separation from Biotech, it appears that the government may wish to offer evidence concerning the circumstances under which defendant Philip was separated from Biotech. To the extent that Mr. MacMillan -- as Philip's boss's boss -- has knowledge of that separation, Mr. MacMillan of course would be barred from testifying about his understanding of that separation should the Court allow this *in limine* motion.

Regarding the motions to sever Count 13 of the superseding indictment (in substance, former Count 15 of the original indictment), Count 13 charges Biotech with making a false statement to the FDA concerning the number of patients that were treated with OP-1 Putty in 2006. In connection with this charge, it appears that the government intends to offer evidence of a meeting that occurred in June 2005 at Biotech headquarters, wherein Mr. MacMillan was present and the issue of the number of patients being treated with OP-1 Putty was allegedly discussed. As a preliminary matter, as set forth *supra* at 4-5, Mr. MacMillan testified in his interview that he did not recall even being *present* at the

meeting, let alone recall a discussion concerning the number of patients being treated with OP-1 Putty. Interview at 6. In any event, were the Court to sever Count 13, any potential testimony that Mr. MacMillan could give on the issue of the number of patients treated with OP-1 Putty in 2006 would no longer be relevant to the case to be tried, thus making Mr. MacMillan even more superfluous to the trial.

In summary, as demonstrated above, Mr. MacMillan is incapable of providing any specific, non-cumulative and probative information concerning the guilt or innocence of any defendant. This is not surprising, because Biotech was the smallest division by any metric among all Stryker divisions, and Mr. MacMillan was (and is) charged with running all of the divisions in the whole company. He cooperated with the government fully and responsibly in the investigative stage of this case, during which the government learned that he has nothing of substance to offer as a witness. As District Judge Gertner put it, the government "should not be allowed to compel the appearance of a witness whose testimony would be irrelevant." *United States v. Manghis*, 2010 WL 349583 (D. Mass. 2010). Mr. MacMillan would, therefore, respectfully request that his subpoena be quashed.

II. IN THE ALTERNATIVE, MR. MACMILLAN REQUESTS THAT HE BE PERMITTED TO TESTIFY AFTER THE WEEK OF JANUARY 9

Should the Court deny his motion to quash, Mr. MacMillan respectfully requests that he be permitted to testify on a day *after* the first week of trial of January 9-13, 2012. During the first week of trial, Mr. MacMillan has long-standing commitments each day that are vitally important to his duties as Chairman and CEO and to the shareholders of Stryker. Those commitments are as follows:

> *Monday, January 9*: Mr. MacMillan is scheduled to attend and present at the National Sales Meeting for Stryker's Patient Handling and EMS Medical Division in San Antonio, TX. At the meeting, Mr. MacMillan will give a "State of the

Company" speech to the sales force and then conduct what amounts to a town hall meeting. This is a yearly keystone event where he is expected to set the company's direction and motivate the sales force.

Tuesday, January 10: Mr. MacMillan is a guest presenter on the CNBC CEO Panel at the JP Morgan Healthcare conference in San Francisco. This conference is widely viewed in the healthcare industry as the single-most important and influential conference for healthcare companies like Stryker and for institutional healthcare investors. It is a high honor for Mr. MacMillan to have been chosen to participate on the CNBC CEO Panel at this conference.

Wednesday, January 11: Mr. MacMillan will make a presentation to institutional investors at the JP Morgan Healthcare Conference, and will speak again at a luncheon. This presentation is the most important presentation that Mr. MacMillan will make to institutional healthcare investors during the entire year. Moreover, later that day, he is meeting with Jeffrey Shuren, the Director of the FDA's Center for Devices and Radiological Health, who will also be attending the conference.

Thursday, January 12: Mr. MacMillan is scheduled to attend and present at the National Sales Meeting for Stryker's Endoscopy, Patient Care and Field Services Division in San Antonio, TX. At the meeting, Mr. MacMillan will again give a forward-looking speech to the sales force and conduct a town hall meeting presentation. After that meeting, he flies overnight to Barcelona, Spain.

Friday, January 13: Mr. MacMillan is scheduled to attend and present at the National Sales Meeting for all of Stryker's European Divisions in Barcelona, Spain. His duties at this meeting are similar to his duties at the foregoing National Sales Meetings.

Again, Mr. MacMillan requests this one-week scheduling relief not because he believes he is above the law, but only so as to meet his commitments to both the Court and to Stryker. At the same time, the government will not be prejudiced by a one-week delay in his testimony, especially considering that a fair portion of the first week of trial will be consumed by motion practice, jury selection and opening statements.

CONCLUSION

For all of the foregoing reasons, Mr. MacMillan respectfully requests that the Court quash his trial subpoena. In the alternative, Mr. MacMillan requests that the Court enter an Order granting Mr. MacMillan relief from testifying as a witness during the first week of trial, from January 9, through 13, 2012.

Respectfully submitted,

STEPHEN P. MACMILLAN

By his attorneys,

/s/ *Peter E. Gelhaar*
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CERTIFICATION PURSUANT TO LOCAL RULE 7.1

I, Peter E. Gelhaar, hereby certify that counsel have conferred and have attempted in good faith to resolve or narrow the issues presented. Specifically, although the government expressed a willingness to schedule Mr. MacMillan's appearance during the week of January 16, 2012, the government was unwilling to withdraw the subpoena.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants.

DATED: December 21, 2011 /s/ *Peter E. Gelhaar*